US PATENT APPLICATION
Docket No. WILB01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: BRIAN R. WILL

Serial No.	10/608,408	Examiner:	Shay, David M.
Filed:	June 27, 2003	Group Art Unit:	3735

For: EYE FIXATION APPARATUS

Date: January 10, 2007

Mail Stop RCE
The Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT UNDER RULE 1.132 TRAVERSING REJECTIONS

I, BRIAN R. WILL, hereby declare under penalty of perjury based on personal first hand knowledge the following to be true and accurate:

1. I write this declaration to overcome and traverse rejections made under Section 103 in the July 14, 2006 Final Office Action. This declaration is submitted in conjunction with a Request for Continued Examination.

2. I am a board certified Ophthalmologist with over 17 years of practice. I have performed over 28,000 LASIK procedures as well as over 10,000 other ocular procedures in that time, and currently perform over 3,000 LASIK procedures per year. I have intimate experience with much of what has been considered state of the art in the field of LASIK and other keratome procedures, using lasers and microkeratome blades, including the devices incorporating the Hellenkamp (U.S. 6,042,594), Clark (U.S. 5,591,174), Curtin

(U.S. 4,173,980) and L'Esperance (E.P. 0372127A1) references, or similar to these references, cited by the Examiner. This declaration is made based on my personal experience and that of my staff of two (2) ophthalmologists within the field.

3. My invention provides an improved apparatus and method for fixing the eye during keratome surgeries, and for adjusting surgical devices to the fixated eyeball during procedures. The improvements relate both to the improved accuracy of the surgery due to reduced distortion of the eyeball and greater precision of positioning, as well as reduced damage to the cornea, sclera and conjunctiva. These improvements are concrete. The improvement in outcomes includes: greater measured improvements in visual acuity for patients; less discomfort for patients during and after surgery; less damage to the cornea, sclera and conjunctiva during surgery; less discomfort for patients with narrow lid openings; and allows patients that have small lid fissures / apertures to undergo LASIK whereas existing technology denies them such an opportunity.

4. Regarding independent claims 1 and 11, a fundamental reason for the improved performance of the apparatus is the criss-cross channel design of the vacuum ring. The criss-cross channel design provides several specific benefits over existing devices:

a. The lands between the channels provide multiple contact points spread over a wider surface, preventing the cornea, sclera and conjunctiva from being displaced into the vacuum channels and providing a more stable contact, preventing "rocking" on the eye.

b. The use of criss-cross channels prevent occlusion of the vacuum source which can lead to loss of vacuum – and loss of eye fixation – during surgical procedures.

c. The use of criss-cross channels markedly reduces deformation of the eye and reduces intraocular pressure – thus it is safer, more comfortable, and provides improved accuracy, especially in Femtosecond procedures.

d. The use of criss-cross channels to distribute vacuum, rather than a vacuum annulus, creates a lower profile device thereby obviating the need to use a lid speculum, and providing more clearance in a tight space during procedures.

e. The surgeon is able to reposition the fixation device if the initial positioning is incorrect, because the criss-cross channels do not cause gross distortion of the cornea, sclera and conjunctiva, whereas existing devices prevent repositioning due to the indentation and elevation of a ring of tissue on the cornea, sclera and conjunctiva when conventional fixation devices are removed.

f. The use of shallow criss-cross channels allows for more rapid and thorough cleaning of the apparatus, providing quicker turnaround time between patients and extending the life of the devices themselves.

g. The addition of X-Y translation guides, see dependent claims 3-10 and 14-21, provide adjustment capabilities built in to the fixation device which allow for superior centration properties in laser procedures.

h. The addition of docking screws, see dependent claims 5, 6, 9, 10, 16, 17, 19, 20 and 21, for docking surgical devices into the fixation aperture, rather than conventional pincer type docking systems, provide smoother docking with less manual dexterity required.

5. The criss-cross channel design, claims 1 and 11, allows a lower vacuum setting to achieve the same fixation of the eye, and the narrowness and cross-orientation prevent significant displacement of the cornea, sclera and conjunctival tissue into the vacuum channels. Existing annular vacuum rings, such as taught by the Hellenkamp and Curtin references cited by Examiner, displace significant amounts of tissue into the vacuum ring cavity, leading to several drawbacks.

a. First, by drawing the ocular tissue into the annulus it can (and often does) damage the ocular tissue. Often this damage does not create problems, but under certain circumstances it can. In one example, if the initial setting of the fixation device is incorrect then the displacement can prevent repositioning because it leaves an indentation and a swollen ridge conforming to the annulus. The annular ring creates a ridge (rather like a "hickey") on the cornea, sclera and conjunctiva – the displaced ring of ocular tissue remains that way for some time. A second attempt at surgery can only be made after this annulus-shaped "hickey" has healed

because it prevents proper re-alignment of the vacuum ring itself. A second example of the problem created is when the displacement causes separation of the conjunctiva from the underlying scleral tissue – a condition called "chemosis." Some patients are more susceptible than others, but with the growth of LASIK and other surgical procedures this is becoming a more and more significant problem. Since the majority of inflammatory tissue in the eye is located in the conjunctiva, trauma to that tissue in the form of chemosis or, trauma in general, can significantly increase the amount of inflammation in the eye following surgery, which can lead to serious inflammatory complications such as Diffuse Lamellar Keratitis, that can markedly alter healing and the surgical result. A third example of problems resulting from conjunctival displacement is that, even without a complete separation such as in chemosis, the damage caused by conjunctival displacement can lead to subconjunctival hemorrhaging, which appears as a red blood spot on the eye. Although not generally dangerous, it is undesirable for the patient (and a poor advertisement for surgeons).

b. The apparatus and method described in claims 1 and 11 reduce these risks in several ways. First, the criss-cross channels are shallow and distributed over a wide area which conforms to the shape of the eyeball, because they are surface grooves rather than an annulus. Second, the separate channels pull the corneal, conjunctival and scleral surface taught between them and provide many lands, conforming to the

natural shape of the eyeball, for contact area. In other words, rather than being drawn into the channels the corneal tissue is held against the lands, resulting in minimal displacement. Third, because the channels are spread over a wide area rather than a narrow ring a lower vacuum pressure can be used to achieve the same stability. The ability to hold the eyeball in place is determined by both the vacuum pressure multiplied by the total area of the channels or annulus (i.e. the absolute force applied), as well as the depth over which the force is distributed (i.e. the wider the base of application, the more stable the support provided by the fixation apparatus – proportional to the moment of inertia). Therefore, multiple points of contact spread over a wider band create a more stable base than narrower annular vacuum rings, or conversely, lesser vacuum pressure is required to achieve comparable stability – which in turn reduces the likelihood of all the complications associated with vacuum fixation devices. For example, the apparatus and method of claims 1 and 11 requires lower vacuum levels than for conventional annular devices, using the system described in Hellenkamp, that I have significant experience with. Although the L'Esperance reference, cited by Examiner, is an improvement over annular designs in this last regard, the porous membrane of L'Esperance is subject to clogging (see ¶ 9, below), and the annular vault necessitates a lid speculum (see ¶¶ 7-8, below).

c. A second advantage of the apparatus and methods of claims 1 and 11 is that they avoid the excessive deformation of the

eyeball, and consequently the cornea, during a LASIK or other keratome procedure, which is caused by annular vacuum rings. This deformation leads to dual problems of less accurate correction due to the distorted cornea, and raised pressure within the eye which can lead to more dangerous complications such as occlusion of the blood supply. The high vacuum and eyeball distortion caused by annular rings frequently result in the cornea being compressed so that it is thinner than normal and it also assumes a completely abnormal shape and contour. Although the eye is somewhat elastic, it does not immediately rebound to its natural shape or thickness after the vacuum or vacuum ring is released. The eyeball distortion and occlusion of the arterial blood supply also renders the iris to be temporarily ischemic, thereby temporarily altering its shape and the normal pupil response time to light and accommodation. These distortions of normal eye conditions are important factors in less than optimal surgical outcomes.

d. In addition, this distortion and compression alters the normal water content of the cornea from its natural state. The accuracy of the LASIK procedure depends on three primary factors: accurate cutting of the keratome flap, accurate placement and control of the Femtosecond and excimer lasers, and the shape and condition of the cornea when it is lazed. Excimer lasers used to photoablate corneal tissue assume a normal state of corneal hydration as well as a predictable corneal contour and shape. Individual variations in the water content of the cornea caused

by corneal compression from the annular vacuum ring cannot be predicted or accounted for by the excimer lazing processes. In addition, most excimer lasers require that the ablation profile be modified on an individual basis to account for the angle of incidence of the excimer beam at the exact point of beam application on the curved corneal surface. Because the annular vacuum ring deforms the eye and the tissue is not immediately elastic following ring removal, the exact shape of the contour to the cornea is no longer known and attempts to precisely compensate for angle of incidence effects on excimer beam efficiency based upon preoperative corneal shape measurements are no longer accurate or valid.

e. Compression of the corneal tissue, caused by annular vacuum rings, also creates errors in creating a predictable flap thickness, as current Femtosecond and keratome devices determine flap depth by measuring from the anterior surface of the cornea only. Tissue compression of the anterior corneal tissue or the entire cornea of only a few microns will cause such a device to create a flap that is significantly thicker than expected. Excessively thick or unpredictable flap thickness is one of the leading sources of error in LASIK surgery and predisposes the subject eye to structural weakness and risk for ectasia. Eye tracking excimer lasers frequently use the iris and pupil as a landmark for reference for the tracking apparatus so as to compensate for intraocular eye movement and as a point reference for the centration of wavefront or topographically guided photoablation procedures. Subjecting the iris to

transient ischemia by high intraocular pressure from annular vacuum rings intraoperatively distorts the pupil and renders the iris less responsive to light and accommodation for a temporary period. These factors measurably reduce the accuracy of centration and thereby adversely effect the accuracy of the refractive treatment.

f. Therefore, based on these various factors: (1) preoperative measurements of corneal thickness, hydration state and contour are not accurate after the eyeball has been grossly deformed by high vacuum pressures; (2) flap thickness based on depth measurements from the anterior surface of the cornea after the tissue is compressed and distorted can no longer accurately predict flap thickness postoperatively; (3) distortion and distention of the iris and pupil due to transient iris ischemia introduces significant error in centration of the intended photoablative procedure as the pupil centroid is displaced from the normal preoperative position; and, (4) the excimer laser can no longer accurately compensate for tissue shape or tissue hydration consistency during the procedure as these factors have been modified intraoperatively by high vacuum. All of these factors create the propensity towards unpredictability of refractive endpoint and cause over and under corrections of the refractive error. Fixation devices such as Hellenkamp and Curtin cause unnecessary deformation: after sucking the sclera up into the vacuum chamber the targeting device flattens the cornea down, compressing the tissue and thereby introducing deformation error.

g. Hellenkamp specifically teaches that the annular-style vacuum ring "cause[s] the cornea to be urged upwardly and to protrude through the aperture 25 of the positioning segment 20..." *See Hellenkamp, col. 7, ll. 30-32.* Claims 1 and 11 significantly reduce the distortion due to the distributed vacuum channels. Lower vacuum is required to begin with since the channels are interspersed between surfaces which approximate the eye's natural shape, so the tissue is held against these lands. Minimal displacement of the cornea into the vacuum channels reduces the distortion of and pressure within the eyeball. And, the use of channels rather than a porous surface prevents clogging which can cause some areas to be held more tightly than other areas – leading to still more distortion as well as other potential complications (discussed below).

h. A third advantage of the apparatus and method of claims 1 and 11 is that the criss-cross channels are less susceptible to occlusion from displacement of the conjunctiva, sclera or cornea into the annulus and from mucus. Partial occlusion can result in some areas being held more tightly than others making those more tightly held areas more susceptible to chemosis or other trauma. Occlusion may also result in loss of vacuum during the surgical procedure with potentially devastating consequences. The Hellenkamp reference, cited by Examiner, specifically discusses some problems caused by displacing the sclera into annular rings, and attempts to solve these problems. The vacuum enhancer of

Hellenkamp is a partial solution to the problem of occlusion, making loss of vacuum less likely, but does not address the other drawbacks of annular designs discussed above. The sclera is still exposed to a continuous hollow annular chamber thereby causing a raised ring on the tissue. The hollow annulus also imposes a high profile, similar to L'Esperance, requiring a lid speculum and attendant disadvantages discussed above at paragraphs 7-8, below. Hellenkamp's solution is limited by the fact that it relies on modifying a conventional annular vacuum ring structure. Hellenkamp, at col. 3, ll. 20-44, discusses displacement of the conjunctiva into an annular chamber and problems of conjunctival separation and damage. Hellenkamp, at col. 3, ll. 20-44, discusses problems of vacuum chamber occlusion caused by displacement of the conjunctiva into the vacuum ring chamber. Hellenkamp, at col. 3, ll.45-61, discusses problems of mucus buildup in annulus-type rings and difficulty in cleaning due to the hardening of residual mucus debris. If buildup and hardening of mucus within an open channel is problematic, as taught by Hellenkamp in 1998, due to the inability to clean out the annulus chamber, then buildup and hardening of mucus is even worse in a porous surface such as taught by L'Esperance in 1988. Residual mucous material embedded in this porous material may introduce unwanted complications from cross contamination between patients, even despite sterilization procedures. Proteins, other biological macromolecules and debris transferred between patients from this porous

membrane that contacts sensitive eye tissue will increase postoperative inflammation and potential infection from viral, bacterial or prion residues. There is simply no effective way to clean the pores taught by L'Esperance so, in a relatively short time, the device will become unusable and require replacement. The apparatus and method of claims 1 and 11 reduce the likelihood of occlusion – through the use of cross-connected vacuum channels – and significantly reduce the other negative effects inherent to annular designs, as discussed above. The criss-cross channels are less subject to blockage because if one channel becomes blocked – for whatever reason – an alternate vacuum path remains. The criss-cross channels are significantly easier to maintain and clean because they are flat and shallow, rather than the vaulted annulus of existing devices.

i. Applicant does not argue that Hellenkamp, L'Esperance or any other reference cited, is non-functioning or invalid. Rather, Applicant through claims 1 and 11 provides unobvious solutions to verified real world problems.

6. The Examiner's Office Action of July 14, 2006, at page 2, states that since the L'Esperance patent states that it only claims to operate "solely upon the optically used area of the anterior surface of the cornea" (Examiner quoting the L'Esperance reference) then damage to the cornea due to the fixation device would "constitute operating on a portion of the eye which was other than the optically used portion of the cornea." I am an ophthalmologist and the Examiner's statement is incorrect – complications from surgery are not

"operating", they are complications. The recognition that a surgical procedure has side effects caused by the surgical devices does not render the side effects – unwanted and unintended – "operating." The Examiner's statement is even more perplexing considering the fact that the Hellenkamp reference, cited by Examiner, discusses some of the problems of corneal damage caused by annular vacuum rings at length. Hellenkamp attempted one method of solution, which turns out to be inadequate in certain critical respects. The goal of my invention, described in claims 1 and 11, which is actually achieved, is to reduce unwanted side effects and complications from surgery, and provide greater accuracy during surgery.

7. The criss-cross channels of my claims 1 and 11 reduce the potential for trauma to the cornea, a leading cause of post-LASIK complications. The incidence of subconjunctival hemorrhage has been estimated as high as 10% or more in LASIK patients. Thus, the problems associated with existing eye fixation apparatus are far from "speculative," as asserted by the Examiner, who provided no references to back up his incorrect assertions of fact. *See, e.g.,* Sun L, Liu G, Ren Y, Li J, Hao J, Liu X, Zhang Y., EFFICACY AND SAFETY OF LASIK IN 10,052 EYES OF 5081 MYOPIC CHINESE PATIENTS. *Journal of Refractive Surgery,* 2005 Sep-Oct; 21(5 Suppl):S633-5. PMID 16212294.

8. The low profile achieved by the criss-cross channel design eliminates the need for a lid speculum in most cases, including patients with narrow ocular fissures and orbits. Higher rates of complications from using annular fixation devices on patients with narrow ocular fissures and orbits, such

as patients of Asian descent, have been documented in medical studies. In at least one peer-reviewed study approximately 28% of Asian LASIK patients experienced prolonged or permanent "dry eye" following LASIK procedures. *See, e.g.,* Albietz JM, Lenton LM, McLennan SG., DRY EYE AFTER LASIK: COMPARISON OF OUTCOMES FOR ASIAN AND CAUCASIAN EYES, *Clinical and Experimental Optometry* 2005 Mar; 88(2):89-96. The study concluded that this was likely due, in part, to damage from the vacuum fixation apparatus caused by the tight fit of the suction ring and keratome device within their narrower orbits. Id, p.95. The criss-cross channels obviate much of this risk. The criss-cross channel design imposes fewer stresses on the cornea and eyeball to begin with. This design also allows use of a low profile, conforming, base which fits under the eyelid, rather than an annular vault, obviating the need for a lid speculum, which is required when using apparatus taught by Hellencamp, L'Esperance, and Curtin. Even in the absence of dry eye complications, lid specula carry the disadvantages of causing greater discomfort to the patient both during and after surgery, and creating space interference for the surgical team in an already tight working space.

9. I have reviewed the L'Esperance references cited by the Examiner, including the newly cited references (US 4,732,148 and US 4,770,172). All the L'Esperance references specifically claim annular vacuum designs applying suction through a permeable (i.e. porous) membrane, and thus all share the drawbacks of the high profile and difficult cleaning requirements of other annulus apparatus. Based on my experience the pores of the L'Esperance design are

quite vulnerable to clogging – as is the case with any porous membrane applied to mucus surfaces. I have found, based on extensive experience in thousands of surgical procedures, that devices such as that taught by L'Esperance have at least two major drawbacks that are not mere "speculation."

a. First, L'Esperance relies on applying suction through a porous surface backed by an annular chamber. The porous surface is subject to clogging by mucus from the conjunctiva surface – all porous surfaces are subject to clogging. This clogging in turn leads to the dual problems of causing blockage of the vacuum path and inadequate cleaning which shortens useful life. Mucus is difficult or impossible to clean out of porous surfaces, especially so after hardening, so the porous membrane device taught by L'Esperance would either have a very short useful life or it would require special cleaning procedures which would make surgical procedures significantly less economical. It is also anticipated that cross contamination from residual mucous material, bacteria and other biological macromolecules in the porous material would introduce significant risk to patients from infection and excessive postoperative inflammation from the transference of foreign biological molecules and material between patients. The Hellenkamp reference discusses the difficult problem of cleaning mucus and attempts to solve the problem by making part of his device disposable – a less than optimum solution. In addition to the danger of loss of vacuum, or uneven vacuum, if the pores become completely clogged during a procedure (due

to inadequate cleaning or other factors) the membrane will adhere to the corneal surface through surface tension of the mucus and water, which could easily cause damage when removed. (As an example, place a wet glass on a smooth surface or coaster – when it is lifted the coaster will adhere to the bottom of the glass.) This kind of force applied to the corneal surface – a delicate structure – can and will cause damage. This danger is especially pronounced in patients who are susceptible to chemosis or have abnormally poor adhesion of the epithelial layer such as a Basement Membrane Dystrophy, which is a very commonly occurring anomaly.

b. A second drawback of the L'Esperance reference, shared by other references cited by the Examiner, is the high profile of the vacuum chamber vault necessitated by annular designs. The high profile requires use of a lid speculum during procedures in order to hold the eyelids back. In a patient with narrow lid fissures, a high-profile vacuum ring such as L'Esperance may not be able to be used at all, with or without a lid speculum. Lid specula increase risks of complications, create more discomfort for the patient and are additional interference in a constrained space requiring significant precision for a successful procedure. The discomfort caused by the high profile apparatus is especially pronounced for patients with narrow lids (see ¶¶ 7 & 8, above). The criss-cross channels solve this problem, which is a real problem, because they create a low profile that can fit under a patient's lid.

10. The X-Y translation capability built in to the eye fixation apparatus, (claims 3-10 and 14-21) and the use of docking screws rather than conventional pincers (claims 5,6, 9, 10, 16, 17, 20 and 21), are also major improvements over the state of the art. The X-Y adjustment capability allows the laser or other surgical apparatus to be slaved to the eyeball, rather than vice versa (e.g. as shown in the Curtis reference, cited by Examiner). Use of translation rods with adjustment knobs, directly on the eye fixation device, greatly reduces the manual dexterity required for adjustments, and provides for more accurate docking of the surgical apparatus. The improvement has been significant, especially in Femtosecond procedures, in achieving superior centration properties.

a. The X-Y translation capability and use of docking screws provides other advantages as well. No fixation device will achieve perfect alignment on a patient's eye. Existing eye fixation devices, represented by Hellenkamp, Curtis and L'Esperance, don't adjust to the eyeball, so surgeons either have to force the eye into alignment by manipulation of the fixation apparatus or, in the case of Femtosecond laser surgery, the laser controls must provide for complicated adjustment capabilities to compensate for x-y offset. Forcing the eye into alignment by manually distorting the fixation apparatus magnifies all of the problems with eye distortion discussed above. Attempting to correct for gross distortions through laser controls requires complicated hardware and software which is expensive and potentially prone to problems. In addition, for microkeratome procedures no adjustment is possible without the x-y

translation capability. The only adjustment provided is for depth of the blade.

b. The x-y translation capability of claims 3-10 and 14-21 allows the surgeon to dock the laser or other apparatus into the fixation device, and make simple adjustments using the docking screws (claims 5,6, 9, 10, 16, 17, 20 and 21) while sighting to an eye with minimal distortions.

c. The addition of adjustment arms, as in claims 2, 13 and 22 allow a surgeon to easily maneuver the device on the eye surface without their fingers obscuring their vision. Additionally, because the surgeon's fingers are holding the adjustment arms – i.e. away from the actual conjunctival surface – there is less chance of scratches or contamination due to inadvertent contact.

11. The experience of myself and my staff has demonstrated the need for these improvements. One must appreciate that ophthalmologic surgery using lasers to reshape the eye, or perform other procedures, frequently involves adjustments in the sub-micron range, so seemingly minor improvements to surgical apparatus can produce significant improvements in patient outcomes and economies. I would not have expended the time, effort and money to develop this new invention if existing devices were fully adequate and did not exhibit known adverse affects upon tissue health and healing during refractive eye surgery procedures..

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED THIS <u>B R Will</u> January 12, 2007
BRIAN R. WILL, MD

Residence:	Vancouver, WA
Citizenship:	United States of America
Post Office address:	8100 NE Parkway Dr. Vancouver, WA 98662